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TO: Food and Drug Administration
Dockets Management Branch, [HFA-305]
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FROM: Sterimatic Limited,
Abnash,
Chalford Hill, Stroud,
Gloucestershire, GL6 8QN, UK.

REFERENCE: As published in Federal Register Vol.67 No 119/Thursday June 20, 2002:
Reference 21 CFR Part 880
Docket No. 01P-0120
RIN 0910-ZA20

SUBJECT: **Medical Devices; Needle-Bearing Devices; Request for Comments and Information.**

AGENCY: Food and Drug Administration, HHS

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The food and Drug Administration (FDA) is issuing this document to invite interested persons to submit information to assist the agency in determining what additional actions, if any, the agency should take to protect healthcare workers from needlestick injuries from medical devices. FDA is taking this action because it is concerned about the significant health risk posed by needlestick and other percutaneous injuries.

Response follows

01P-0120

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Response

In response to the above request, we submit the following information and comment.

Hazardous Needlesticks can be prevented with appropriate safety needle technology.

Since the enactment of the Needlestick Safety and Prevention Act, an increasing number of 'safety' needle products continue to be offered to healthcare workers. Almost all of these products offer at best only limited protection, and at worst, can potentially increase the risk of needlestick. This is because these new safety devices require manual activation by the user after needle use.

It is important here to understand the context and cause of needlestick events.

1 Context. Hazardous needlesticks occur from the moment of needle point insertion when needle is contaminated with blood, throughout needle use on patient, during withdrawal and prior to safe disposal. 26percent of needlesticks occur during use (CDC). No manually activated safety system will protect user during needle use.

2 Cause. Most needlesticks occur through:

1. Patient reaction and behaviour during use.

2. User tiredness, distraction, stress, jostling etc., during and after needle use and prior to disposal.

Any safety needle device which is dependant on user manual activation under such circumstances and conditions can therefore not only fail to prevent, but can potentially increase needlestick injuries, since it creates the need for the user to concentrate further on performing an additional procedure involving manual activity with the device.

It is however possible to effectively prevent hazardous needlesticks with safety needle devices. Provided such devices are:

1. Automatically activated without the need for any user action.

2. Provided devices are automatically activated from moment of needle insertion and protect user throughout needle insertion, application, withdrawal and disposal.

Such automatic (passive) safety needle devices are currently available and have been in continuous use at NYC hospitals (NYU Medical Centre and Mount Sinai) for some years. Full product references are available from these hospitals.

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Role of FDA and OSHA to provide new criteria for the required safety performance of needle devices.

In order to achieve effective protection of healthcare workers from needlestick injuries, FDA and OSHA need to provide new criteria for the required safety performance of needle devices. The essential criteria are:

All safety needle devices should be automatically (passively) activated at moment of needlepoint insertion (risk creation), and permanently protect user throughout needle usage, withdrawal and disposal.

Such safety technology is well proven and fully available. (All manufacturers have capability of producing product to these criteria). It is the only effective means of preventing needlesticks and can be achieved with FDA and OSHA action in mandating required performance criteria for safety needles. Without such action, potentially unsafe needle protection technology will continue to put healthcare workers at risk.

We would be pleased to provide any further information or assistance that FDA or OSHA may request in this important matter.

John Parry
Chairman

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